



July 31, 2023

*Submitted electronically via regulations.gov*

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Comment Request: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements, Draft Guidance for Industry; Docket No. FDA-2023-D-0451**

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) comment request regarding draft guidance for industry entitled "Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry." As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at [www.FMI.org](http://www.FMI.org).

FMI shares FDA's commitment, as stated in the draft guidance, to providing consumers with information to enhance their ability to make informed choices about the foods they buy and eat. Health and nutrition are of the utmost importance to the food industry and for years, FMI and its members have recognized the need to help consumers navigate the varying labeling attributes on today's products. We remain committed to transparency for consumers and continuously strive to name plant-based foods in a clear way and make nutrition and other food information easily accessible to consumers.

**General Comments**

As noted above, FMI shares FDA's goals of supporting clear and transparent labeling that will help consumers make well-informed purchasing decisions to help meet their dietary needs and support healthy eating patterns. We appreciate FDA's thoughtful approach to this guidance, including the Agency's September 2018 notice requesting information on the "Use of the Names



of Dairy Foods in the Labeling of Plant-Based Products”<sup>1</sup> and the Agency’s subsequent review of the over 13,000 comments received. We also appreciate FDA’s recognition of the developments in both availability and consumption of plant-based milk alternatives, and the important reasons such as allergies, intolerances, or lifestyle choices (e.g., vegan), that consumers select these products. These changes in market and consumer demands make it clear that FDA’s guidance is both timely and necessary to support this important food category and to achieve our shared goals as stated above. FMI agrees that a guidance-based approach is appropriate here given the diversity of products and plant-based ingredients, rapid pace of innovation in the plant-based milk category, and ongoing evolution of nutrition recommendations. These factors would make rulemaking a challenge as it could be outdated before it is even finalized.

We also support FDA’s data-driven approach, which takes into account consumer understanding of plant-based milk alternatives, including data submitted in response to the September 2018 notice, as well as focus groups conducted by FDA, in its recommendations. The draft guidance indicates that in FDA focus groups, “most participants were not confused about plant-based milk alternatives containing milk” and that “milk” is “strongly rooted in consumers’ vocabulary when describing and talking about plant-based milk alternatives.”<sup>2</sup>

FMI agrees with FDA’s conclusion that consumers generally do not mistake plant-based milk alternatives for milk, and strongly supports the Agency’s determination in the draft guidance that the terms soy milk, almond milk, as well as terms that use the term “beverage” or “drink” (e.g. “soy beverage”) have been established as common or usual names for these products based on common usage. This clarification will help to preserve the ability to label these products in a way that is consistent with existing practices and understood by consumers, while at the same time balancing the key First Amendment principles FDA cites in the guidance document. We note that FDA’s reference to First Amendment considerations is helpful and appropriate. FDA points out important developments in First Amendment case law and underscores the importance of focusing on whether speech is truthful and not misleading for consumers. This is necessarily a case-by-case assessment and will change over time, again supporting that guidance is the appropriate vehicle to address the labeling of plant-based milk alternatives and other plant-based foods.

The FDA recognition that terms such as soy milk and almond milk are appropriate common or usual names is helpful in relation to the state laws enacted in the past five years that restrict the use of certain conventional food terms, such as meat, poultry, and rice, in the naming of novel alternative foods, such as cell-cultured and plant-based meat and poultry products. In some states these laws include express recognition that foods are not considered mislabeled if they bear a prominent qualifier that the food is “plant-based”, “veggie”, or other similar terms, but in other cases this recognition is not provided in the law. The FDA recognition, at least in the context of plant-based milk alternatives, that a product name that uses the standardized or

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<sup>1</sup> See 83 FR 49103.

<sup>2</sup> Food and Drug Administration, *Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry, Draft Guidance* (February 2023).

conventional term in a way that clearly indicates it is distinct from the traditional version of the food (e.g., almond milk”), provides helpful support for the truthful and non-misleading labeling of other plant-based products in states with relevant laws.

We also believe FDA is on strong ground in not strictly applying the imitation food labeling regulation to plant-based milks. Imitation foods are defined as those that “substitute for and resemble[] another food but [are] nutritionally inferior to that food.” Section 403(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(c)) deems a food to be misbranded if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated. FDA states in the draft guidance that not all plant-based milk alternatives meet the definition; and to the extent any do, the Agency intends to exercise enforcement discretion.

FDA reasons that Congress’ intent when enacting Section 403(c) of the FD&C Act was to protect the consumer from uninformed purchase of inferior substitute product. FDA goes on to conclude that this is unnecessary here given that consumers generally do not mistake plant-based milk alternatives as milk. We agree with this conclusion and appreciate FDA’s clarification that it does not generally consider plant-based milk alternatives to fall under the imitation food labeling regulation and will exercise enforcement discretion with respect to this rule as applied to plant-based milk alternatives. FDA’s analysis in the draft guidance supports not only enforcement discretion, but also a conclusion that the regulation does not apply so long as the product is properly labeled.

As FDA notes, consumers readily recognize that plant-based milks are not milk, and in fact specifically seek out the products for that very reason. For many consumers, plant-based milks do not “substitute” for cow’s milk; rather, for consumers with allergies, intolerances, or specific dietary preferences, cow’s milk would not be a viable choice. This would support a determination that plant-based milk alternatives do not broadly substitute for cow’s milk and do not meet the definition of an imitation food. Where plant-based milks are clearly labeled to distinguish the products from milk, the “imitation” regulation should not apply. Depending on the product and its positioning, strictly requiring “imitation” labeling could be misleading and would raise significant First Amendment concerns. A wide range of nutrient profiles are possible among diverse products, and a bright-line test (e.g., any reduction in any nutrient present at 2% of the DV) does not align with a common understanding of the term “imitation.” Including the word “imitation” could also unnecessarily deter consumers from selecting plant-based milk alternatives to address allergies, intolerances, lifestyle, or other needs.

## **Specific Comments and Requests for Additional Clarification**

### **1. The voluntary nutrient statement goes beyond what is needed to achieve its intended goal and would benefit from rescission or significant revision**

FDA's desire to provide additional nutrition information to help consumers make informed choices is well intended. Although we agree with the goal behind FDA's efforts to help ensure consumers fully understand the products they are buying, FMI is concerned that the suggested template for voluntary statements to call out nutrient differences is overly formulaic and detailed, inconsistent with other agency labeling precedent, and potentially unhelpful to consumers. As explained below, we ask FDA to rescind or significantly revise the tentative guidance on voluntary nutrient statements. It would be more consistent with First Amendment principles to recommend a case-by-case review of the specific context for individual products to ensure that all claims are truthful and not misleading and to limit recommendations about nutrient statements to *material* information, consistent with the FD&C Act.<sup>3</sup>

The draft guidance suggests that the statement should address nutritional differences for 9 nutrients (calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, and vitamin B12). As such, a product containing lower amounts than milk of all 9 nutrients would be recommended to bear the following statement.

"\*Contains lower amounts of calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, and vitamin B12 than milk."

The draft guidance further recommends that this statement should be visually connected to the name of the product if space allows and should appear on the front panel of the food label. If consumers do not understand nutritional differences between dairy milk and plant-based milks, it does not necessarily follow that statements about individual nutrients are the best way—or an effective approach—to address consumer needs. Further, the recommended front panel placement runs counter to the fact that very few FDA-mandated or -recommended labeling elements appear on the front panel.<sup>4</sup> The use of a front panel statement to address nutritional differences could overstate their significance or be alarming to consumers in a way that is not merited, particularly if the nutritional differences are slight or involve non-shortfall nutrients. For that reason, we believe the recommended approach is overly formulaic and doesn't account for the varying levels of importance that the nutritional differences would have for particular formulations or for particular consumers.

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<sup>3</sup> 21 U.S.C. 343(a); 321(n).

<sup>4</sup> The mandatory elements that must appear on the front panel are limited to the product name and the net quantity of contents statement. If the product bears a representation about the characterizing flavor of the product, the flavor labeling would need to be included on the front panel as well.

By focusing on nutrients that are non-shortfall nutrients and that are not mandatory nutrients in the Nutrition Facts panel, including vitamin A, magnesium, phosphorous, riboflavin, and vitamin B12, we are concerned that the draft guidance misapplies the “material facts” standard under the FD&C Act. We question how it can be the case that differences in these nutrients are so material as to merit a recommended front-panel call out, yet they are not mandatory to declare in the Nutrition Facts panel. Indeed, it could be confusing to consumers to see the differences in these nutrients highlighted but not be able to find information about non-shortfall nutrients on product labels, including cow’s milk labels.

FMI also notes that other food categories are not required or recommended to differentiate in levels of nutrients. For instance, within the dairy milk category, buffalo milk and goat’s milk vary in nutritional content from cow’s milk and yet these foods are not required or recommended to bear a nutritional comparison statement. Recommending the voluntary nutrient statements for plant-based milk alternatives could convey an outsized importance to this information.

Relatedly, it is very difficult to convey in a limited label space all (or even most or many) considerations for choosing a particular food. The statement recommended by FDA appears to be focused on consumers who have the desire or option to consume either dairy milk or plant-based milk. For consumers who cannot consume dairy or seek out plant-based milks for health or other preferences (e.g., allergies, intolerances, veganism, or other preferences) it is unhelpful and irrelevant to call out milk as a reference point.

FMI encourages FDA to consider educational efforts and advice that consumers consult with nutrition professionals to understand the pros and cons of dietary choices including plant-based milk alternatives. This would also allow the space (that labels do not typically allow) to provide information about the non-shortfall nutrients, if FDA determines that information is material, without resulting in consumer confusion when those nutrients are not declared on product labels.

**2. In the alternative, if FDA maintains an approach similar to the recommended voluntary nutrient statements in the draft guidance, the agency should recommend a more general statement and exclude non-shortfall nutrients from the assessment**

In the alternative, to the extent FDA moves forward with a recommended voluntary nutrient statement, we have two key recommendations. First, we ask FDA to provide examples of a more streamlined voluntary nutrient statement that calls attention to the nutritional differences at a high level. For example, a general statement such as “See [side/back] panel for nutritional comparison to milk” or “This product is nutritionally different than milk” placed on the same panel as the nutritional facts panel or on another panel of the label. This would be more consistent with other disclosure statements related to nutrient content, such as the “see nutrition information for [name of specific nutrient] content” statement that is required to

accompany nutrient content claims when a product contains more than specified levels of total fat, saturated fat, cholesterol, or sodium.”<sup>5</sup>

Second, the voluntary nutrient statement should focus on those nutrients that are nutrients of public health concern, as identified in the Dietary Guidelines for Americans, and that are mandatory to declare in the Nutrition Facts panel, which include calcium, vitamin D, and potassium. The draft guidance indicates that FDA has focused on calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B12 because the Dairy Group is noted in the Dietary Guidelines to be a key contributor of these nutrients; however, of these nutrients only calcium, vitamin D, and potassium are noted as nutrients of public health concern across all age groups.

FMI asks that FDA focus solely on those nutrients for which the Dairy Group is a key contributor that are also nutrients of public health concern as identified by the Dietary Guidelines for Americans (i.e., calcium, vitamin D, and potassium). This will help ensure that the information highlighted on the front panel of the label is limited to the information most material to consumers.

### **3. FDA should ensure the discussion regarding identification of the plant source in the product name fully implements the flexibility offered by FDA’s food naming regulations**

In the draft guidance, FDA specifies that for plant-based milk alternatives, the term “milk” (or “beverage” or “drink”) should be qualified by the plant source of the food. The draft guidance further specifies that the name may be a single word, multiple words, or hyphenated and that for blends of two or more plant-sources, the name should accurately convey to the consumer that multiple plant sources are present. The examples noted include:

“Soy and Nut Milk Blend” (for a product that contains a blend of soy, almonds, and cashews)

“7 Grain Plant-Milk Blend” (for a product that contains a blend of only grains (e.g., oats, wheat, barley, rice))

Although these examples work well for the products they describe, FMI members have indicated that this guidance may be overly simplistic and not reflect the full extent of the flexibility provided in FDA’s existing food naming regulations, particularly as applied to blends of plant-based milks.

FDA’s discussion of common or usual names in the draft guidance is helpful in many respects. As noted above, FMI strongly supports the FDA recognition that names such as almond milk or soy milk or terms that use “beverage” or “drink” are appropriately considered common or usual

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<sup>5</sup> 21 CFR 101.13(h).

names. As numerous examples illustrate, the mere use of a standardized term on a food label does not necessarily subject a food to a standard of identity, provided the standardized term is sufficiently qualified to distinguish the product from the standardized food.<sup>6</sup> The use of a standardized term on a label must be read in the context of the entire statement of identity, the label as a whole, and the nature of the food. The use of “milk” as part of a plant-based identity statement is consistent with this longstanding precedent. We likewise support FDA’s clarification that the naming for plant-based milks can be a single word, multiple words, or hyphenated; and view this clarification as consistent with the common or usual name regulation, which is not overly prescriptive as to the format of the naming.

The draft guidance, however, in some respects appears less flexible than the principles set out in FDA’s naming regulations. Under 21 CFR 102.5, common or usual names must be “as simple and direct” as possible and must call out “the basic nature of the food **or** its characterizing properties **or** ingredients” (emphasis added). Under 101.3, when there is no established common or usual name, a food may be identified by an “appropriately descriptive term.” These are flexible regulations that do not impose specific language.

FDA should reconsider draft guidance that appears to suggest that specific ingredient callouts are always recommended in a common or usual name. FDA should recognize the case-by-case nature of the assessment, which is largely guided by the specific product at issue, including which ingredients if any are characterizing, the number of plant-based sources, and other factors. For a guidance document, examples should be flagged as appropriate possibilities and not as the only means of compliance, consistent with Good Guidance Practices and First Amendment principles for commercial speech.

In particular, FDA’s examples (e.g., “Walnut & Cashew Milk”; “Soy and Nut Milk Blend”) depict relatively simple formulas. The identity statements suggested are sound possibilities for some products but are not the only ways to convey the basic nature of plant-based milk alternatives. We ask FDA to revisit the naming discussion with the inherent flexibility of the FDA regulations in mind and to clarify that any examples offered are merely examples.

Further, for more complex formulations, the approach to call out plant-based sources may not be appropriate or required under FDA’s naming regulations for all products. For example, a nut blend (e.g., cashew and almond blend) might be combined with a fruit blend, and contain additional plant-based ingredients such as soy protein isolates. Based on the current draft

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<sup>6</sup> For example, FDA has recognized that “yogurt drink” is not subject to the yogurt standard of identity (FDA Memoranda to National Conference of Interstate Milk Shippers, Memoranda of Information M-I 10-6 June 17, 2010 (Q&A), at 4, <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM216462.pdf>) and that a product can bear the term “mayo” so long as it bears the statement “spread and dressing” to distinguish it from standardized mayonnaise (See FDA close out letter to the August 12, 2015 Warning Letter issued to Hampton Creek Foods). Likewise, examples such as “bread” show that qualified standardized terms can be used as part of product names (e.g., without invoking the relevant standards).

guidance, it is unclear if FDA is recommending such a product to be labeled as “nut, fruit, and soy blend product,” which might be too long and complex for easy consumer recognition and understanding when certain ingredients (e.g., the soy protein isolates) are contained only in small amounts and contribute more to the nutritional content than to the flavor or basic nature of the product.

FDA should recognize that a variety of approaches could be appropriate to name plant-based milks and blends of plant-based ingredients. For example, the name could identify the primary characterizing ingredient(s) and allow more flexibility for ingredients that are less characterizing or present at a lower level (e.g., “nut milk blend with other plant-based ingredients”). Another example is a blend of three or more plant-based milks where none is more characterizing than the others, which could appropriately be labeled using a more general name such as “Plant-based Milk Blend”. We ask FDA to provide additional examples of appropriate names for complex blends, including more simplified names, and to recognize that a variety of naming options would comply with the relevant regulations.

More broadly, as FDA works to develop its separate draft guidance on the labeling of other plant-based foods, we urge the agency to keep in mind the flexibility offered by FDA’s naming regulations. This context will be even more important for other plant-based foods, such as Plant-Based Burgers or Spreads, which typically feature a similar flavor profile across products and for which a wide variety of ingredients may be used. For example, taking the draft guidance to its reasonable extreme and applying it outside of plant-based milks, spreads from different companies could be made from different oils and have different names, yet have identical or nearly similar appearances, flavors, and culinary uses. Presumably, the similarities among products and the lack of a particular characterizing flavor factored into FDA’s decision to close out its 2015 Warning Letter to Hampton Foods after the company clarified its use of “Mayo” and added a prominent “Dressing and Spread” identity with no specific ingredients called out as part of the product identity.<sup>7</sup>

In summary, we believe that for many plant-based products, simple identity statements that may not call out particular plant-based sources are appropriate. While identity statements that name specific plant-based ingredients are appropriate and may be required where the food already has an established common or usual name or is uniquely characterized by one or two ingredients, this may not be the case for all products. Many plant-based foods (including some plant-based milks and other dairy products, as well as most spreads, veggie burgers, links, and other foods) have multiple synergistic ingredients and no single one or even a combination of two or three is uniquely characterizing. And for some products, calling out some ingredients could actually create confusion because the product does not taste like the ingredient – for

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<sup>7</sup> Warning Letter to Hampton Creek Foods, Inc. (Aug. 12, 2015); Letter from Joshua Schiller, Bois, Schiller and Flexner LLP, to Anam Drumheller, Food and Drug Administration (Sept. 16, 2015); *see also* Beth Kowitt, *The Mayo Wars Just Ended*, *Fortune*, Dec. 17, 2015, <http://fortune.com/2015/12/17/hampton-creek-just-mayo-fda/>.



example, coconut, peas, or cabbage. The use of innovative ingredients in creative ways is likely to increase in the future. For such products, simple names like "Plant-based milk," "Veggie Burger" or "Plant-based Spread" are often appropriate. We ask FDA to take an approach in the final guidance on plant-based milks, as well as the forthcoming draft guidance on the labeling of plant-based foods, that sufficiently accounts for this flexibility under the naming regulations.

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We greatly appreciate the opportunity to comment on the draft guidance on labeling of plant-based milk alternatives. FMI is happy to answer any questions regarding our comments and look forward to continuing to work with FDA on this important product sector.

Sincerely,

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Dana Mullen Graber  
Senior Counsel, Legal and Regulatory Affairs

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Madalyn Farrar  
Manager, Government Relations